No. 13259

IN THE

United States Court of Appeals

FOR THE NINTH CIRCUIT

WOODARD LABORATORIES, INC., DEAN D. MURPHY and JOHN L. SULLIVAN,

Appellants,

vs.

UNITED STATES OF AMERICA,

Appellee.

APPELLEE'S BRIEF.

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I.

Statement of Jurisdiction.

Pursuant to 21 U. S. C. 331(a), 21 U. S. C. 333(a), and 18 U. S. C. 3231, the District Court had jurisdiction to try the defendants-appellants.

Under 28 U. S. C. 1291, this Court has authority to review the judgment of the District Court.

II.

Statement of Facts.

A. Summation of Case.

The Information filed in this case charges the defendants in ten counts with violations of the Federal Food, Drug, and Cosmetic Act, resulting from the interstate shipment of certain drugs alleged to be adulterated and misbranded. [R. 3.] The ten counts involve a

total of five interstate shipments of the drug "Estrocrine" whose strength, the Information charged, was below that declared on the labels; each shipment is the basis for two counts, one relating to misbranding and one to adulteration.

Upon arraignment, each defendant entered pleas of not guilty to each of the ten counts. [R. 21-22.] Each defendant filed a waiver of jury. [R. 22-25.]

After a two-day trial before the Court sitting without a jury, each of the defendants was found guilty on Counts 1, 3, 5, 7, and 9, and not guilty[1] on Counts 2, 4, 6, 8, and 10. [R. 344.] On December 3, 1951, the District Court sentenced the defendants: Woodward Laboratories, Inc., to pay a fine of $500 on each of Counts 1, 3, 5, 7, and 9, or a total fine of $2500 [R. 28]; Dean D. Murphy to pay a fine of $50 on each of Counts 1, 3, 5, 7, and 9, or a total fine of $250 [R. 29-30]; and John L. Sullivan to pay a fine of $50 on each of Counts 1, 3, 5, 7, and 9, or a total fine of $250. [R. 31.]

On December 5, 1951, each of the defendants filed a Notice of Appeal. [R. 32-33.]

B. The Government's Evidence.

Most of the facts upon which this case was based are undisputed and are covered by the Stipulation of Facts. [Ex. 1 and R. 354.] The admitted facts eliminated any issue as to the interstate shipments, the making of

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[1]The reason for the Court's not guilty verdict on the even numbered counts was explained by the Court [R. 344]:

> "And while, of course, they are technically guilty, insofar as the even-numbered counts are concerned, inasmuch as they are dependent upon the same facts . . . they are found not guilty inasmuch as they may not be found guilty of two offenses which are dependent upon the same facts."

the shipments by the defendants, the identity of the labels, and the identity of the samples obtained and analyzed by the Government.

At the trial, only one issue remained: Was the strength of these drugs below that which is declared on their labels?

Each of the five counts on which the defendants were found guilty is predicated upon a different shipment of the drug "Estrocrine." A typical label states in pertinent part: "Each tablet contains: 0.022 mg. alpha estradiol." [R. 4 and 354.] The Government's evidence established that the tablets actually contained far less than this declared amount of alpha-estradiol.

Both Government witnesses are outstanding authorities in the field of pharmaceutical chemistry. Jonas Carol has been a chemist with the United States Food and Drug Administration for 21 years, and he is Chief of the Synthetic Branch of the Division of Pharmaceutical Chemistry. [R. 36.] Practically all of his work has been in the analysis of drugs and in the development of methods for their analysis; during the past six years he was engaged almost exclusively in developing methods of analysis for estrogenic hormones. [R. 36.] Alpha-estradiol, the active ingredient of the drug here in question, is one of the estrogenic hormones. [R. 38.]

Mr. Carol gives instruction on methods of hormone analysis to many chemists who come to study with the Food and Drug Administration; these chemists are sent by commercial pharmaceutical houses, educational institutions, and domestic and foreign law enforcement agencies. [R. 36-37.] He has had 22 papers published in scientific journals on drug chemistry and the chemistry of hormones. [R. 36.] He is frequently called to participate

in the granting of doctors' degrees at Georgetown University, passing upon theses submitted by candidates in the fields of hormone chemistry or spectrophotometric analysis. [R. 36-37.]

During his association with the Food and Drug Administration, he has analyzed many thousands of drugs, of which about 1000 were drugs containing alpha-estradiol. [R. 37-38.]

Mr. Carol and his associates, after doing experimental work, wrote the method of assay for alpha-estradiol in tablets that was published in the volume called United States Pharmacopoeia XIV, which is the latest revision of that compendium. [R. 38-39.] Known as the U. S. P., it is published by the United States Pharmacopoeial Convention[1a] which meets periodically, and has standing committees that develop standards for drugs and write monographs describing the drugs and the tests that are made to establish their purity and composition. [R. 38.]

The U. S. P. is recognized as an official compendium by the Federal Food, Drug, and Cosmetic Act. [21 U. S. C. 321(j), 351(b), 352(e), and 352(g).]

In addition to the method of assay for alpha-estradiol published in U. S. P. XIV, there are a number of other common procedures for determining the amount of alpha-estradiol present in a tablet. [R. 40.] All of the methods involve two major steps: (1) the *extraction* of the alpha-estradiol from the excipients (inert ingredients) with which it is entableted, and (2) the *measurement* of the extracted alpha-estradiol. [R. 39-40.]

[1a]The history and objectives of this non-governmental organization are described in "History of the Pharmacopoeia," by E. Fullerton Cook, Food, Drug, and Cosmetic Law Quarterly, Vol. 1, No. 4, p. 518 (C. C. H., December, 1946).

The principles involved in the extraction process for alpha-estradiol have been used for at least 50 years, and, as described in a book published in 1920, they are essentially the same as those in U. S. P. XIV. [R. 41, 281-282.] The earliest method for the measurement of alpha-estradiol was published in 1933. [R. 41 and 282.] The U. S. P. XIV method is an adaptation and refinement of the earlier methods of extraction and measurement [R. 41], and can be used with relatively simple equipment. [R. 293.]

Mr. Carol assayed samples taken from all five of the shipments upon which the Information was based, using the infra-red method of analysis because it gives both qualitative and quantitative results at the same time, and because he wished to double check on the U. S. P. method that was used by other chemists with the Food and Drug Administration in analyzing samples from these shipments. [R. 42-43, 299.] Mr. Carol conducted special extraction and experimental procedures to assure complete extraction of the alpha-estradiol in these tablets. [R. 43-45, 300-301.] *His assays established that the amount of alpha-estradiol actually present per tablet in the five shipments involved ranged from 23% to 68% of the amount declared in the label* or, put another way, *from 32% to 77% below the declared amount.* [R. 42-47.][2]

Under the supervision of Mr. Carol, Dr. Edward Haenni, an associate of Mr. Carol's who worked with him in the development of the U. S. P. method, used that method to analyze samples taken from three of the

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[2]A breakdown of Mr. Carol's findings with respect to each sample he analyzed appears in the Appendix as Appendix A.

shipments in question. [R. 47-48, 50.] *Dr. Haenni found that the alpha-estradiol content of the tablets in those three shipments ranged from 32% to 63% of the amount declared in the label* or, *from 37% to 68% below the declared amount.* [R. 48-49.][3]

Dr. Daniel Banes has been a chemist with the Food and Drug Administration since 1939, specializing in drug analysis since 1940, and doing his chief work since 1948 in research on the analysis of estrogenic hormone preparations. [R. 51.] He is employed in the Division and Branch that is headed by Mr. Carol. [R. 51.] That group succeeded in isolating three new female sex hormones related to alpha-estradiol. [R. 52.]

Dr. Banes' Ph. D. thesis dealt with a specific type of estrogenic hormone. [R. 52.] He has written 12 papers on drug analysis, and the later papers have been devoted to estrogenic hormones. [R. 52.] He is a referee on estrogenic synthetic hormones for the Association of Official Agricultural Chemists, and he has delivered papers dealing with estrogenic hormones before the American Chemical Society. [R. 53.]

In developing the U. S. P. method, Dr. Carol's group tested a large number of samples containing various amounts of alpha-estradiol, and concluded that this method would give complete extraction and permit an accurate assay of the alpha-estradiol present. [R. 54.] These samples included a number of commercially prepared tablets containing approximately 22 micrograms[4] of alpha-

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[3]A breakdown of Dr. Haenni's findings with respect to each sample he analyzed appears in the Appendix as Appendix B.

[4]Note that 22 micrograms are the equivalent of 0.022 milligrams, the alpha-estradiol potency claimed for the tablets in this case. [R. 68.]

estradiol per tablet. [R. 283-284.] In their investigational work, they made certain that the alpha-estradiol present in a preparation would be extracted no matter what the mixture was. [R. 55.]

Dr. Banes assayed samples taken from all five of the shipments in question, using the U. S. P. method; *his assays establish that the amount of alpha-estradiol actually present per tablet ranged from 30% to 73% of the amount declared in the label* or, *from 27% to 70% below the labeled potency.* [R. 53-61.][5] Dr. Banes conducted extensive special extraction and experimental procedures to verify that his findings accurately reported the alpha-estradiol content of these tablets. [R. 55-56, 58-60, 61-62.]

C. The Defendants' Evidence.

Defendant John L. Sullivan is general manager of defendant corporation, Woodard Laboratories, Inc. [R. 67.] Woodard Laboratories itself did not manufacture the tablets in question but ordered them made by Crest Laboratories. [R. 68-74.] Woodard furnished Crest with the alpha-estradiol used in the manufacture of the tablets. [R. 75.]

The five shipments here involved came from a total of three lots of tablets made by Crest; each lot contained tablets of two potencies—22 micrograms and 110 micrograms. [R. 68-71.] Woodard received these tablets from Crest in bulk form and then packaged, labeled, and shipped them as stipulated. [Ex. 1; R. 71.]

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[5]A breakdown of Dr. Banes' findings with respect to each sample he analyzed appears in the Appendix as Appendix C.

Although defendants had been having this drug manufactured at least since *April, 1949,* they made no effort to have any assay or analysis of its potency made by any laboratory until late in *May, 1950,* and then only *after* receiving notice of hearing from the Food and Drug Administration (pursuant to 21 U. S. C. 335) stating that samples had been obtained from these shipments and found below the labeled strength. [R. 72, 74, and 75-77.]

Harry Rosenzweig is a production chemist employed by International Hormones, Inc., of Brooklyn, New York. [R. 78-79.] That firm manufactured the alpha-estradiol which Woodard purchased and ordered sent to Crest to be used in manufacturing the tablets that are the subject of this case. [R. 78-82, 75.] The alpha-estradiol which Woodard thereby obtained apparently came from three different lots manufactured by International Hormones although one order by Woodard was filled from the stock of one Silas, the California representative of International Hormones, and Mr. Rosenzweig had no personal knowledge that Silas filled this order from any batch about which he was testifying. [R. 81, 87-88, 96-97.] Silas was not called as a witness. Mr. Rosenzweig testified in his deposition that he made certain analyses regarding one of those lots to determine the "melting point" and the "optical rotation," but did not have complete records with him. [R. 80-82, 87.] He did not know who made the analyses of the other two shipments. [R. 87.]

Joseph G. Galindo is vice-president of Crest Laboratories and was the firm's production manager at the time it manufactured the instant tablets for Woodard. [R. 98.] Mr. Galindo claimed, and identified work-

sheets which purported to show, meticulous care by Crest in manufacturing the tablets for Woodard. [Exs. B-H, incl.; R. 107-115.]

Upon cross-examination, however, something considerably less than the meticulous care claimed was demonstrated. In a number of instances, the worksheets did not bear any initials which would show who performed certain alleged operations. [R. 133-135.] Mr. Galindo had testified that there was always a manufacturing loss in the tableting process, yet was compelled to admit that certain worksheets [Exs. F and G] showed no such loss. [R. 153.] Nor could he explain the *gain* in weight between the granulating and the tableting process shown in Exhibit G, and "surmised" that this was an error. [R. 154.] He could not explain why Exhibit H did not show the weight after tableting although this was the one batch which he had testified was made directly under his supervision and that of two other members of his staff. [R. 136-137.] Exhibit H declares "Batch size 7,000" but actually represents 14,000 tablets—7,000 with alpha-estradiol and excipients, and 7,000 with excipients alone. [R. 138-139.] And although Mr. Galindo testified two separate batches were made, only one worksheet was used with but one set of computations. [R. 138-139.]

Something is lost in the course of the manufacturing process, and Mr. Galindo did not know whether that something was the alpha-estradiol. [R. 134, 140-141.] The alpha-estradiol used in manufacturing a batch of 110,000 tablets weighs about one-ninth to one-tenth of an ounce. [R. 154.] Basing his opinion upon visual observation rather than scientific assay, Mr. Galindo stated

he did not believe that the manufacturing loss could comprise a large part of the alpha-estradiol. [R. 155-156.] *He admitted that no laboratory assay or analysis was made by Crest Laboratories of any of these tablets.* [R. 132-133.]

Don Carlos Atkins is director of laboratories of Crest Laboratories, having been employed by the firm in July, 1950. [R. 157.] Mr. Atkins testified that a number of the excipients (inert ingredients which give a tablet bulk and shape) present in the tablets here involved could "interfere" with the light readings contemplated by the U. S. P. method of assay. [R. 159-172.] However, he declared that this "interference" would give a *higher* reading of alpha-estradiol than was actually present in the tablets. [R. 164, 169-173.] He believes the U. S. P. method is not suitable for the assay of these tablets. [R. 179.]

The first contact Mr. Atkins had with *any* alpha-estradiol was at the Crest Laboratories where he did not begin working until July of 1950. [R. 181-182.] After some uncertain testimony, he reiterated his earlier statement that the interference, if any, caused by the excipients would give a *higher* reading of alpha-estradiol, which would indicate a higher potency than the tablet actually had. [R. 184-187, 192, 198.]

Under cross-examination, Mr. Atkins stated he had made no analysis of the tablets involved in this case. [R. 180.] When the Court asked him whether he carried out any experiments "with these particular tablets," he replied, "No, sir, I did not." [R. 201.] However, when the Court pressed this inquiry, he admitted that he did do some experiments on these tablets "with the U. S. P.

procedure, and we were unable to obtain a reading at all." [R. 201.] Upon further probing by the Court, it developed that when Mr. Atkins said, *"we were unable to obtain a reading at all,"* he meant that he *"came out with a greater quantity of estradiol"* than was actually supposed to be in the tablets. [R. 202.]

Dr. C. E. P. Jeffreys is a consulting chemist and technical director of Truesdail Laboratories, Inc. [R. 203.] Prior to July, 1950, he was asked by Crest Laboratories to run an assay of the estradiol content of some tablets but refused to do it because he didn't feel there was any acceptable method for commercial testing. [R. 204-205.] However, in July of 1950, he received an advance copy of U. S. P. XIV, and he then agreed to assay the tablets in question for Woodard by the U. S. P. procedure. [R. 204-205.] His assay was limited to a sample from but one of the three lots in question. [R. 218.] His first results showed the presence of 8.1 micrograms, whereas subsequent readings showed 9.5 and 9.1 micrograms. [R. 205-206, 219-220.] He believed that the U. S. P. method of assay did not extract all of the alpha-estradiol present in such a tablet and was not a suitable method. [R. 214-215.]

On direct examination, Dr. Jeffreys advanced the theory that a substantial amount of alpha-estradiol in these tablets adhered to the surfaces of the excipients and was not separated from those surfaces by the U. S. P. method of assay. [R. 207-215.] On cross-examination, however, he admitted he really didn't know whether the alpha-estradiol would stick to the surfaces of any of the excipients in these tablets. [R. 222.] He conceded it was possible that the reason he got low results was that there

was no more alpha-estradiol present in the tablets. [R. 223.] (On rebuttal, Mr. Carol testified that if some of the alpha-estradiol were adsorbed in the initial process of the U. S. P. procedure, it would be extracted in the subsequent stages; he knew this to be a fact from his experimental work. [R. 295.])

Dr. Jeffreys testified that a chemist should check his results by running an assay on a blank tablet alongside that of the estradiol tablet [R. 211-212], but he admitted he ran no assay on a blank tablet and made no re-extractions to check his results. [R. 221.]

This was Dr. Jeffreys' first assay of alpha-estradiol tablets. [R. 226, 204-205.] He did not believe there was any method known to science that is suitable for the assay of a tablet represented to contain 22 micrograms of alpha-estradiol. [R. 227-228.]

Dr. Robert Ellis Hoyt is employed in the division of laboratories in the Cedars of Lebanon Hospital. [R. 229.] His major work has been in bacteriology, urinology, and pathology. [R. 230.] He has taught these subjects in a number of schools. [R. 230-233.] He has published about 35 papers, only one of which he would say is in a field related to estradiol. [R. 233.]

At the request of Woodard Laboratories, Dr. Hoyt made certain assays of tablets furnished by Crest; these included "placebo tablets" and tablets alleged to contain 23.3 micrograms of alpha-estradiol. [R. 234, Ex. H.] He testified he made a total of four assays, three of which were U. S. P.

Dr. Hoyt's first assay involved the use of "pure estradiol" to check the method of assay; beginning with 20 micrograms of estradiol, he stated he recovered only

14.5 micrograms by the U. S. P. method. [R. 239-240.] His second assay involved the tablets represented to contain 23.3 micrograms of alpha-estradiol; he stated he recovered only 10.1 micrograms by the U. S. P. procedure. [R. 243.] His third assay involved adding 20 micrograms of alpha-estradiol per tablet to blank or "placebo" tablets; he stated he recovered only 10.1 micrograms. [R. 245.] His fourth assay involved the tablets represented to contain 23.3 micrograms of alpha-estradiol; he stated he extracted 16.4 micrograms by an assay procedure which modified the U. S. P. method. [R. 246-247.]

Dr. Hoyt concluded it was not possible to recover all of the alpha-estradiol by the U. S. P. method when it was held in excipients of the sort that were found in these tablets. [R. 245-246, 248-249.]

On cross-examination, it was brought out that Dr. Hoyt's background has been primarily in bacteriology and pathology; while he was once employed as a biochemist, he did not run assays on estrogenic hormones. [R. 249-250.] None of the papers he wrote dealt with estrogenic hormones. [R. 250.] He ran three different sets of assays but brought his work sheets on only one of those sets to court. [R. 253-255.] He did not use the U. S. P. Reference Standard of alpha-estradiol in running his first assay. [R. 252.] (The U. S. P. Reference Standard of estradiol is of proven purity, comes sealed, may be obtained from the U. S. P. at Philadelphia, and assures the investigator he is using a very high grade of estradiol. [R. 291-292.])

In doing his assays, Dr. Hoyt did not check back on the excipient mass at any time to determine whether any

alpha-estradiol was in fact left there, saying "that didn't seem to be relevant." [R. 255, 258.]

Dr. Hoyt had not run any U. S. P. assay on alpha-estradiol before making these analyses. [R. 256.] *In fact, this was the first time he had analyzed an alpha-estradiol tablet by any method.* [R. 259.]

Dr. Hoyt advised the Court he was sure that the exact amount of alpha-estradiol in the tablets here involved could be determined, but that none of *these* tablets had been submitted to him for an analysis. [R. 263.]

Dr. Harry Sobel is head of the department of biochemistry at the Cedars of Lebanon Hospital. [R. 264.] His major interests have been steroids, endocrinology, and clinical chemistry. [R. 265.] He has written 13 papers, of which he stated eight have something to do with the subject of steroids or estrogen or estradiol, directly or indirectly. [R. 266.] He and Dr. Hoyt together conducted the assays about which Dr. Hoyt testified. [R. 266.]

Dr. Sobel believes the U. S. P. procedure for alpha-estradiol extracts not only alpha-estradiol but also beta-estradiol and estrones. [R. 267.] (However, the Government's rebuttal witness, Mr. Carol, testified that if this were true, the final reading would be higher. [R. 287.])

Dr. Sobel described a number of stages in the U. S. P. assay of these tablets where he thought that loss of alpha-estradiol might occur. [R. 268-275.] However, he had done no experimental work to establish whether

any loss actually occurred at any of those places. [R. 275-278.]

After both sides had rested, and counsel for the Government had concluded his argument, counsel for defendants was permitted to reopen the case to introduce the deposition of Mrs. Elizabeth Adam Weiss. [R. 308.] Earlier, counsel had declared he would not offer this deposition because he was absolutely convinced that this chemist was not correct in her assay, in the way she did it, or in her conclusions. [R. 97, 302-303.]

On direct examination, Mrs. Weiss testified about three U. S. P. assays she made in September and November of 1950 with respect to samples of the tablets in question. She gave her results as ranging from 21.2 micrograms to 26 micrograms per tablet. [R. 315-317.]

On cross-examination, Mrs. Weiss testified that she made three other assays with respect to samples of these tablets in June of 1950. She gave her results as ranging from 10.5 micrograms to 17 micrograms per tablet. [R. 337-338.] She used the Carol-Moliter-Haenni method in making these assays, and in her opinion, the results obtained by this method should not vary much from the results obtained by the U. S. P. method. [R. 337, 341.]

On October 10, 1950, she wrote to Mr. Sullivan suggesting that the tablets were not mixed properly in the manufacturing process and therefore varied in their estradiol content. [Ex. 2.]

III.

Statutory Provisions Involved.

Federal Food, Drug and Cosmetic Act.

"21 U. S. C. 351. Adulterated drugs and devices.

A drug or device shall be deemed to be adulterated—

(c) If it is not subject to the provisions of paragraph (b) of this section, and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

"21 U. S. C. 352. Misbranded drugs and devices.

A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular."

"21 U. S. C. 331. Prohibited acts.

The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

"21 U. S. C. 333. Penalties—Violation of section 331.

(a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine."

IV.
Question Involved.

Is there substantial evidence in the record to support the judgment of the District Court?

V.
Summary of Argument.

A. The Judgment of the District Court Must Be Sustained if There Is Substantial Evidence to Support It.

Appellants challenge the sufficiency of the evidence upon which they were convicted. The judgment of the trial court must be sustained if there is substantial evidence to support it, taking the view most favorable to the Government.

The Government did not rely upon circumstantial evidence, but solely upon demonstrable and direct evidence. Accordingly, the rule applicable with respect to circumstantial evidence is not pertinent.

B. The Evidence Which Supports the Judgment of the District Court Is Not Only Substantial but Overwhelming.

The judgment of the trial court is supported by substantial evidence of the most compelling character.

Mr. Carol and Dr. Banes are concededly outstanding authorities in the field of hormones analysis, with special competence in the analysis of tablets containing alpha-estradiol. They analyzed the tablets in question by various methods of assay and found them seriously deficient in alpha-estradiol content.

Chemists who testified for the defense found comparable deficiencies in alpha-estradiol, but speculated that their results were caused by alleged defects in the U. S. P. method of assay rather than by actual deficiencies in the

tablets. None of the defense witnesses had had any extensive experience in assaying alpha-estradiol tablets, and for a number of them this was the first contact with such tablets. It developed that the alleged "defects" in the U. S. P. method of assay, even if they existed, would have tended to give a *higher* reading of alpha-estradiol and would therefore have been in the defendants' favor.

Appellants point to evidence regarding the manufacture of these tablets and assert it "conclusively" demonstrates the presence of 22 micrograms of alpha-estradiol per tablet. But such "evidence" was shown to be permeated with discrepancies, omissions, and admitted errors, and was completely discredited.

Appellants' attack upon the U. S. P. method of assay rests upon unfounded assumptions. Furthermore, the Government's testimony was based upon other methods in addition to the U. S. P. method, with practically uniform results.

C. The District Court Did Not "Misconceive" or "Misapply" Any Legal Principles.

The trial court at first excluded Exhibit H, a worksheet that purported to show how alpha-estradiol tablets *other than those here involved* were manufactured. But when defense counsel made it clear that he intended to use this worksheet, together with subsequent tests made upon such tablets, in attempting to attack the soundness of the U. S. P. method of assay, Government counsel withdrew his objection and the Court admitted the worksheet in evidence.

Appellants make a strained argument to the effect that the Court's initial refusal to admit this evidence shows

that the Court disregarded this line of evidence after it was admitted. There is no support in the Record for such a contention. Rather, the Record plainly establishes that the trial court gave special attention to this evidence as a result of which defense counsel sought and obtained permission to reopen the case after both sides had rested and after Government counsel had concluded his argument.

The Information charges that the drugs in question were adulterated within the meaning of 21 U. S. C. 351(c) because their strength was below that which they purported to possess.

Appellants suggest that portions of Section 351(b) are applicable and that this would require the determination as to the strength of these tablets to be made by the U. S. P. method of assay alone. But the U. S. P. did not recognize alpha-estradiol until *after* defendants made the shipments in question. Since Section 351(b) applies only when an official compedium such as the U. S. P. has recognized a particular drug at the time of the alleged violative act, it can have no application here.

Under Section 351(c), there is no restriction whatever as to the method of assay which may be employed.

D. Other Contentions Advanced by Appellants Are Also Without Merit.

The Government's witnesses used a number of sound procedures, including the U. S. P. method of assay, to obtain and verify their results. This is in keeping with fundamental principles of scientific investigation, and by no means indicates any flaw in the U. S. P. method.

Appellants are misinformed when they say that the $2500 fine imposed upon the corporate defendant is the

largest imposed upon any defendant in a food and drug case in 1951.

Persons who ship drugs interstate have the responsibility of ascertaining that their drugs are not in violation of the Federal Food, Drug, and Cosmetic Act since the innocent public is wholly helpless in such matters.

VI.

Argument.

A. The Judgment of the District Court Must Be Sustained if There Is Substantial Evidence to Support It.

The appellants were tried and convicted by the District Court sitting without a jury. Appellants now challenge the sufficiency of the evidence upon which they were convicted. Under such circumstances, the function of the Appellate Court is clear:

> "It is not for us to weigh the evidence or to determine the credibility of witnesses. The verdict of a jury must be sustained if there is substantial evidence, taking the view most favorable to the Government, to support it."

Glasser v. United States (1942), 315 U. S. 60, 80;

McCoy v. United States (C. A. 9, 1948), 169 F. 2d 776, 787, cert den. 335 U. S. 898;

Karn v. United States (C. A. 9, 1946), 158 F. 2d 568, 569;

Kelling v. United States (C. A. 10, 1951), 193 F. 2d 299, 301-302;

Sharp v. United States (C. A. 6, 1952), 195 F. 2d 997, 998.

In Henderson v. United States (C. A. 9, 1944), 143 F. 2d 681, this Court said at page 682:

> "It is a familiar principle, which it is our duty to apply, that an appellate court will indulge all reasonable presumptions in support of the rulings of a trial court and therefore that it will draw all inferences permissible from the record, and in determining whether evidence is sufficient to sustain a conviction, will consider the evidence most favorably to the prosecution . . ."

Appellants argue that "whether the evidence is sufficient to sustain the judgment depends upon whether all of the substantial evidence is as consistent with a reasonable hypothesis of innocence as with guilt." (App. Op. Br. p. 22.) Even if such a rule were applicable here, it would not help appellants since, as we shall demonstrate, none of the substantial evidence in this case is as consistent with a reasonable hypothesis of innocence as with guilt. But the rule, so heavily relied upon by appellants, has no bearing here. It is invoked only where a conviction is based upon circumstantial evidence. Thus in *Karn v. United States* (C. A. 9, 1946), 158 F. 2d 568, this Court observed on page 570:

> "*The prosecution relied entirely upon circumstantial evidence* for a conviction. It is sufficient to say that *under such circumstances* the evidence must not only be consistent with guilt, but inconsistent with every reasonable hypothesis of innocence . . . (Citing authorities.)" (Emphasis added.)

In the instant case, the prosecution relied solely upon demonstrable and direct evidence and not upon circumstantial evidence.

B. The Evidence Which Supports the Judgment of the District Court Is Not Only Substantial but Overwhelming.

The judgment of the District Court, we submit, is supported by substantial evidence of the most compelling character. Appellants necessarily concede that the Government's witnesses are "men of unquestioned competence." (App. Op. Br. p. 7.) Mr. Carol and Dr. Banes are beyond question among the country's foremost authorities in the field of hormone analysis, with extensive experience in the analysis of tablets containing alpha-estradiol in varying potencies.

It was Mr. Carol and Dr. Banes who developed and adapted procedures for the assay of such tablets by the use of relatively simple equipment, procedures which were reviewed, accepted, and published by the United States Pharmacopoeia. [R. 38-39, 282-283.]

At the trial, the only issue was whether the Estrocrine Tablets shipped by appellants contained 22 micrograms of alpha-estradiol per tablet as declared in the label, or whether they contained a lesser strength as charged by the Government. Using a number of different methods of assay including the U. S. P. method, and repeatedly verifying, double checking, and confirming the accuracy of their results, the Government witnesses found the tablets to be seriously deficient in their alpha-estradiol content.

Significantly, those defense witnesses who analyzed the actual Estrocrine Tablets in question found com-

parable deficiencies.[6] (App. Op. Br. p. 23.) A number of chemists produced by the defense had not even assayed tablets taken from the shipments upon which the Information was based. [R. 180, 263, 266.] However, all of the defense witnesses[7] chose to attribute these deficiencies not to any real lack of alpha-estradiol in the tablets but to alleged defects in the U. S. P. method of assay.

Some of these defense witnesses had never before assayed alpha-estradiol tablets [R. 226, 259, and see 182], yet they advanced a multitude of reasons why they thought the U. S. P. method was not suitable for the assay of these tablets. One witness speculated that the excipients present in the tablets might "interfere" with the results, yet he admitted that such "interference," if any there were, would give a *higher* reading of alpha-estradiol and would therefore be in the defendants' favor. [R. 186.] Another witness thought that the U. S. P. method was not selective enough and would reflect not only alpha-estradiol, but also beta-estradiol and estrones. [R. 267.] If this were true, it would also give a higher alpha-estradiol reading and thus again favor the defendants. [R. 287.]

The Government's witnesses testified that the U. S. P. method had been most carefully developed after years of study and extensive experimental and commercial testing to assure complete extraction and accurate measurement

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[6]Of course, Elizabeth Weiss, one of the defendants' expert witnesses, found no deficiencies in one series of assays, but her testimony in this respect is subject to the serious infirmity that before being offered it was discredited by the defense itself. [R. 315-317, 97, 302-303.]

[7]Except Elizabeth Adam Weiss, who suggested that the fault lay in the manufacturing process. [Ex. 2, letter dated Oct. 10, 1950.]

of the alpha-estradiol present in the tablets regardless of the excipients used or the potency of the tablet. [R. 54, 55, 281-286.]

A defense argument comparable to that urged here was rejected in *Strong, Cobb & Co., Inc. v. United States* (C. A. 6, 1939), 103 F. 2d 671. On page 674, the Court said:

> *"The analyses of the Government chemists are attacked as incorrect. It is said that since the cold tablets contained a number of other ingredients,* such as cascara sagrada, podophyllin, resin jalap, powdered camphor, oleoresin capsicum, and powdered starch, *a strong interference necessarily arose which would greatly affect the accuracy of the analyses.* However, *three of the Government chemists, qualified experts, used methods of analysis which were not identical, and arrived at practically the same result. This is substantial evidence of the correctness of the analyses.* The Government chemists all stated that *the effect of the interfering factor on the result would be negligible.* Moreover, three chemists, two witnesses for the Government and one for appellant, stated in effect that *the presence of the interfering elements would tend to make the acetanilid content higher than it actually was.* Since the adulteration found was a substantial deficiency in acetanilid and quinine sulphate, *the error, if any, resulting from the presence of the interfering elements, would be favorable to appellant rather than prejudicial."* (Emphasis added.)

The almost complete parallel to the instant situation is evident.

Another contention of appellants is that these tablets were properly manufactured under conditions that should

have produced a 22 microgram tablet plus a 5% overage of alpha-estradiol. The assertion is made that Mr. Galindo's testimony and worksheets regarding the manufacturing process are "uncontradicted and unimpeached," with the inference that such evidence was *conclusive* of the central issue—whether the drug contained 22 micrograms of alpha-estradiol when introduced into interstate commerce by the appellants. (App. Op. Br. pp. 29-30.)

Let us examine this contention. To state that Mr. Galindo's testimony stands "uncontradicted and unimpeached" is to disregard the Record completely. Both his testimony and the worksheets he identified were demonstrated to be permeated with discrepancies, omissions, and admitted errors, and were obviously wholly unreliable.[8] [R. 133-145, 153-156.] Rarely, we submit, does a record so clearly reflect the utter discrediting of evidence given by a particular witness as in the case of the Galindo testimony and worksheets. Yet appellants would urge this testimony as "conclusive."

The so-called "manufacturing controls" exercised by Crest disintegrated under scrutiny. It is noteworthy, too, that Crest did not at any time assay *any* of the Estrocrine tablets it manufactured [R. 133], so that its vice-president, Mr. Galindo, was hardly in a position to testify even inconclusively about the central issue of this case—the alpha-estradiol content of the tablets.

In attacking the validity of the U. S. P. method of assay, appellants say that the method may be suitable for a higher potency tablet but not for the lower potency tablets involved in this case. (App. Op. Br. pp. 30-31.)

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[8]See our summary of Mr. Galindo's testimony, *supra,* at page 8.

They point out that Crest manufactured both a 22-microgram tablet and a 110-microgram tablet for them, yet the Information deals only with the 22-microgram tablets. We quote from page 31 of Appellants' Brief:

> "No claim has been made by the Government at any time that the 110 mcg. products were below the labeled potency. This fact is important for this reason: *It certainly may be assumed that if there had been any question about the potency of the 110 mcg. product a charge would likewise have been made against it.*" (Emphasis added.)

Obviously, no such assumption can be made. There is no showing that the 110-microgram product was ever introduced into interstate commerce or sampled by the Food and Drug Administration. In fact, Mr. Carol testified he had not analyzed any of the 110-microgram Estrocrine tablets, and that no one in the Food and Drug Administration had obtained such tablets for analysis. [R. 297-298.] This wholly conjectural argument of appellants not only rests upon unfounded assumptions, but has no bearing whatever upon any issue in this case. How a failure to charge appellants with respect to their 110-microgram tablets proves or disproves anything about the U. S. P. method of assay or even remotely affects the Government's evidence that their 22-microgram tablets were substantially below their labeled potency, passes understanding.

We submit that the District Court's judgment is overwhelmingly supported by substantial evidence.

C. The District Court Did Not "Misconceive" or "Misapply" Any Legal Principles.

Appellants make a long and tortuous argument in an effort to show that the trial court disregarded the testimony of Dr. Hoyt and Dr. Sobel, and that such action was improper. (App. Op. Br. pp. 32-37.) We respectfully refer the Court to our summary of the testimony of these two witnesses as set forth in our Statement of the Case, *supra* at pages 12-15, and we submit that if the lower court had disregarded their testimony, it would have exercised a sound judicial discretion. We are satisfied, however, and the Record affirmatively shows, that the trial court gave full consideration and careful attention to the testimony of these witnesses—as, for that matter, it gave to all of the witnesses—and simply concluded that the testimony of Dr. Hoyt and Dr. Sobel did not affect or disturb that of Mr. Carol and Dr. Banes.

Appellants try to support their assertion by referring to a colloquy with the lower court regarding a ruling in which the Court, on objection of Government counsel, at first excluded Exhibit H, the Crest Laboratories work-sheet purporting to show how the tablets were made which were later used by Dr. Hoyt and Dr. Sobel. Both the Court and Government counsel thought that defense counsel was simply seeking to inject evidence of assays performed by Dr. Hoyt and Dr. Sobel on tablets other than those involved in this case. Quite properly, the Court said: ". . . his testimony . . . would be entirely immaterial, because it is a different tablet." [R. 122.] After defense counsel clarified and limited the

purpose of this evidence, indicating he was attempting thereby to discredit the U. S. P. method of assay, Government counsel withdrew his objection and the Court admitted the evidence. [R. 126-127.]

If the trial court eventually chose to discount the weight to be given the testimony of Dr. Hoyt and Dr. Sobel, it was because it concluded that these witnesses had failed to discredit that method of assay. As the trier of the facts, this was certainly within the Court's prerogative.

The lower court's position regarding the testimony of these witnesses was brought out clearly in the course of the final argument, demonstrating the Court's convincing logic and grasp of the technical concepts involved:

[R. 301]:

> The Court: ". . . The question in the mind of the court is the absence of any testimony on the part of the defendants as to assays made by the defendants to determine the amount of alpha-estradiol in these tablets."

[R. 304]:

> The Court: "In case you misunderstood my question, I did not mean why didn't you come in with an analysis made under the U. S. P. procedure and method, because I realize that in your defense you have been attempting to show the inaccuracy and inefficiency of the U. S. P. method."
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> * * * * * * * *
>
> The Court: "But, of course, one of the things that would have shown that very clearly would be, for instance, if other methods had been used, because the important question is: What was the quantity of micrograms in that tablet?"
>
> Mr. Elson: "That is right."

The Court: "So that, if you had no faith in one system, then, of course you put on men who had no faith in that system, for that purpose. But the simplest, the most effective way to prove that would have been to have men testify who used other systems, who, after making analyses, would tell you, for instance, that there were 22 micrograms in that tablet. I asked Dr. Hoyt that question.

I asked Dr. Hoyt, 'If they had submitted to you the particular tablets involved here, could you have made an analysis that would accurately have told us the number of micrograms in it?'

He said, 'Yes, I believe I could.'

Now, just assume that he could. Then, of course, with all this testimony where he tears down this other system, if he could testify that actually on these tablets that these chemists have run their tests on to show there are 6 micrograms where there are supposed to be 22, 15 where there are supposed to be 22, and so on, 'By using' such and such 'method, I have run a test analysis that shows that actually there were 22 micrograms in there,' if that evidence was available, surely it would have been produced here in court. If he could have made an analysis by any recognized or reputable method that would have shown 22 micrograms in those particular tablets, surely you would have produced that evidence."

Manifestly, it appeared to the District Court that the Government's witnesses had established the presence of substantially less than 22 micrograms of alpha-estradiol in these tablets. Testimony of defense witnesses, insofar as they had examined these tablets, was to the same effect, but they contended that the U. S. P. method of assay was not sound. Yet one of the defense witnesses,

Dr. Hoyt, assured the Court that had these tablets been submitted to him he could have made an accurate assay of their alpha-estradiol content by another method. [R. 263.] If that were true, and if *such* an assay would disclose the alpha-estradiol content of these tablets to be up to the declared strength, evidence of *that* assay would have implemented the contention that the U. S. P. method was inaccurate. Such evidence, if available, would surely have been produced, and the failure to produce it was a factor which the Court was entitled to consider in its appraisal of the evidence in the case. The propriety of these reflections is sustained in the observations made by this Court in the recent case of *C-O-Two Fire Equipment Co. and Maynard Laswell v. United States* (C. A. 9, May 29, 1952, No. 12964), F. 2d, on page 12 of the slip opinion:

> "In the instant situation appellants have not come forward with any satisfactory explanation for the admitted price uniformity, nor was any evidence introduced to dissipate the inference of conspiracy arising from the history of licensing agreements with minimum price maintenance provisions, save for the bare statement that such provisions were abrogated. Appellants, in their brief, advise this court that 'a great deal of evidence could have been offered below on costs, economics, and so forth.' While that may well be true, it brings to mind the thought of Shakespeare '* * * oftentimes excusing of a fault doth make the fault the worse by the excuse.' At least it does not make appellants' position any better, since evidence which could have been offered, but was not, is as nothing."

Appellants suggest that the trial court in effect shifted the burden of proof upon the defendants. (App. Op. Br.

pp. 21 and 44.) This, plainly, the Court did not do. The burden of proving every material allegation of fact beyond a reasonable doubt was of course upon the Government and remained there, but the Government did not have to establish its case beyond *all* doubt. (*Pasadena Research Laboratories, Inc. v. United States* (C. A. 9, 1948), 169 F. 2d 375, 379, cert. den., 335 U. S. 853.) The Government's evidence established at the very least the *prima facie* validity of the various methods of assay used by its witnesses, including the U. S. P. method. To the extent that the defendants chose to attack the U. S. P. method, it was incumbent upon them to adduce evidence sufficient to discredit that method. This they did not do, and the trial court merely suggested one line of testimony which, if available, might have helped the defendants. And acting upon this suggestion, defense counsel sought and obtained permission to reopen the case, after both sides had rested and after Government counsel had concluded his argument, for the purpose of introducing the deposition of Mrs. Weiss. [R. 308-309.]

Tied in with appellants' argument on this point is the relationship between 21 U. S. C. 351(b) and 21 U. S. C. 351(c). (App. Op. Br. pp. 39-46.) Both of these provisions specify circumstances under which a drug or device shall be deemed to be adulterated. Section 351(b) by its terms is applicable only to a drug which "purports to be or is represented as a drug the name of which is recognized in an official compendium." Such a drug is adulterated if "its strength differs from . . . the standard set forth in such compendium." However, the adulteration counts in the instant Information do not charge violation of Section 351(b) but rather of Section 351(c).

Section 351(c) declares that a drug is adulterated, *if it is not subject to Section 351(b),* and if "its strength differs from . . . that which it purports or is represented to possess."

As stipulated, the five shipments in question were all made prior to *June, 1950.* [Ex. 1.] The United States Pharmacopoeia—an official compendium under 21 U. S. C. 321(j)—did not recognize alpha-estradiol tablets until *November, 1950.* [R. 281.] Consequently, at the time these shipments were made, the drug was not recognized in an official compendium and hence could not be considered adulterated within the meaning of 21 U. S. C. 351(b). The defendants could be held criminally responsible under 21 U. S. C. 331(a) and 333(a) for the shipment of these drugs only if they were adulterated at the time when they were introduced into interstate commerce. (*Pasadena Research Laboratories, Inc. v. United States* (C. A. 9, 1948), 169 F. 2d 375, 380, cert den., 335 U. S. 853.) Accordingly, the drugs in these shipments, being below their declared potency when introduced into interstate commerce months before their recognition in the U. S. P., were adulterated under the terms of Section 351(c) rather than Section 351(b).

Section 351(b), for the reasons stated, clearly has no application to the instant case. Therefore, the requirement in that subsection that the method of assay set forth in an official compendium shall be used to determine whether there is a deviation from the standard prescribed by such compendium, is entirely immaterial here. Where, as here, the charge is that a drug is adulterated under 21 U. S. C. 351(c), there is no restriction whatever as to the method of assay which may be employed. Here, the Government

did use the U. S. P. method, but it also relied upon other methods, and a variety of corroborative techniques and analytical procedures, and there was no objection to the introduction of any of this evidence.

Only when the trial court expressed concern over defendants' failure to implement their attack on the U. S. P. method by presenting affirmative testimony, based upon other available methods of assay, that their tablets did in fact contain 22 micrograms of alpha-estradiol—only then did defendants advance the theory, with which the trial court properly disagreed, that evidence based upon such other methods would not be admissible because of the requirements of Section 351(b). [R. 305-307.]

D. Other Contentions Advanced by Appellants Are Also Without Merit.

Appellants criticize the Government's witnesses for using any method of assay other than the U. S. P. method. (App. Op. Br. pp. 28-29, 40-41, and Appendix 17.) We suggest it was eminently proper and in keeping with fundamental principles of scientific investigation to use any sound procedure, including the U. S. P. method, for obtaining and verifying their results. This is a standard practice of the Food and Drug Administration whenever possible. [R. 299.] An important virtue of the U. S. P. method is that "it can be used with relatively simple equipment." [R. 293.] On the other hand, the infrared method used by Mr. Carol "is the most informative and most definite method that we have available." [R. 42.] The results obtained by all of the Government's chemists based upon assays of different portions of the same samples were "comparable" with only "slight variations" [R. 294-295], and all showed the drugs to be seri-

ously below their labeled potency. (See Appendices A, B and C, *infra.*)

Appellants were sentenced as follows: the corporate defendant to pay a fine of $2500, and the individual defendants to pay a fine of $250 each. [R. 28-31.] Speaking of the fine imposed upon the corporation, appellants declare they are informed it was the largest imposed upon any defendant in a food and drug case in 1951. (App. Op. Br. pp. 4 and 47.) This would be wholly immaterial even if true, but appellants are misinformed.[9]

That the trial court chose to assess a substantial penalty is indicative of its recognition of the seriousness of the offense. The drugs in question are female sex hormones

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[9]The amount of sentence is discretionary with the trial court within the limits prescribed by the particular statute and will not be considered on appeal. (See Cyclopedia Federal Procedure (2d Ed.), Vol. 9, Secs. 4537-4540; *Williams v. New York,* 337 U. S. 241 (1949); *Feinberg v. United States,* 2 F. 2d 955, 958 (C. A. 8, 1924).)

The following are among the sentences imposed under the Federal Food, Drug, and Cosmetic Act in 1951:

(a) *United States v. Coburn Farm Products Corp. and Julius Cohen* (S. D. N. Y., Docket C-132-213, Jan. 17, 1951), individual defendant fined $3750.

(b) *United States v. Charleston Drug Co. and Frank C. Harp* (D. Nev., Docket No. 12166, March 8, 1951, individual defendant fined $2500 and put on probation for year on condition that he pay the fine and violate no laws.

(c) *United States v. Fisher Drug Co. and Harold C. Jenkins* (D. Nev., Docket No. 12164, March 8, 1951), individual defendant fined $2500 and put on probation for one year on condition that he pay the fine and violate no laws.

(d) *United States v. Enos A. Hilterbrand* (N. D. Texas, Docket No. 12870, Nov. 28, 1951), defendant sentenced to two years in penitentiary.

(e) *United States v. Diamond State Poultry Co., Inc* (D. Del., Docket Nos. CR 705 and 726, May 21, 1951), total fine of $3000 ($2250 on Docket No. CR 705 and $750 on Docket No. CR 726).

(f) *United States v. Frigid Food Products, Inc.* (W. D. Tenn., Docket No. CR 7950, Dec. 7, 1951), defendant fined $4000.

which were "to be dispensed only by or on the prescription of a physician." [R. 38, 8, 354.] Of necessity, the physician must rely upon the integrity of the product and the vigilance of the Food and Drug Administration. He cannot stop to have assays made of every drug he dispenses.

> "The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."
>
> *United States v. Dotterweich* (1943), 320 U. S. 277, 280.

A drug distributor has an absolute responsibility for adulterated or misbranded drugs that he introduces into interstate commerce.

> "Hardship there doubtless may be under a statute which . . . penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."
>
> *United States v. Dotterweich* (1943), 320 U. S. 277, 284.

Nor is it any defense for the distributor that he was relying upon the integrity of the manufacturer. (*United States v. Parfait Powder Puff Co., Inc.* (C. A. 7, 1947),

163 F. 2d 1008, cert. den., 332 U. S. 851.) Of course, the interstate distributor may immunize himself from the penalties of the law by obtaining a valid guaranty from the manufacturer, thereby shifting criminal responsibility to the latter. (21 U. S. C. 333(c)(2); *Barnes v. United States* (C. A. 9, 1944), 142 F. 2d 648, 650.) Here the defendants produced no guaranty from the manufacturer, and neither the defendants nor the manufacturer had any assays made to check the potency of these tablets until after the Food and Drug Administration notified the defendants that their interstate shipments were in violation of the law. [R. 74, 132-133.] See *Pasadena Research Laboratories, Inc. v. United States* (C. A. 9, 1948), 169 F. 2d 375, 385-386, cert. den., 335 U. S. 853, where this Court considered similar evidence of "poor manufacturing controls."

VII.

Conclusion.

It is submitted that no error was committed by the lower court and that its judgment should be affirmed.

Respectfully submitted,

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APPENDIX A.

Findings of Jonas Carol

(Infrared Method of Assay)

Count	Sample No.	Woodard Lot No.	Date of Analysis	Milligrams Per Tablet	Micrograms Per Tablet	Percent of Declared Strength
I and II	29-794 K	497567	1-20-50	.015	15	68
			8-6-51	.015	15	68
III and IV	49-677 K	897618	4-14-50	.014	14	63
V and VI	49-693 K	107694	5-31-50	.006	6	28
			8-6-51	.005	5	23
VII and VIII	53-254 K	497567	1-20-50	.015	15	68
IX and X	88-164 K	107694	6-13-50	.006	6	28

APPENDIX B

Findings of Dr. Edward Haenni

(U. S. P. Method of Assay)

Count	Sample No.	Woodard Lot No.	Date of Analysis	Milligrams Per Tablet	Micrograms Per Tablet	Percent of Declared Strength
III and IV	49-677 K	897618	4-14-50	.014	14	63
V and VI	49-693 K	107694	5-31-50	.007	7	32
IX and X	88-164 K	107694	6-13-50	.007	7	32

APPENDIX C

Findings of Dr. Daniel Banes

(U. S. P. Method of Assay)

Count	Sample No.	Woodard Lot No.	Date of Analysis	Milligrams Per Tablet	Micrograms Per Tablet	Percent of Declared Strength
I and II	29-794 K	497567	8-6-51	.016	16	73
III and IV	49-677 K	897618	8-6-51	.016	16	73
V and VI	49-693 K	107694	8-6-51	.0068	6.8	31
VII and VIII	53-254 K	497567	8-6-51	.016	16	73
IX and X	88-164 K	107694	8-6-51	.0066	6.6	30